AMENDMENTS TO THE CLAIMS

We claim:

1. (Currently amended) An osmotic device comprising:

a core comprising a first amount licofelone and at least one osmotic agent or osmopolymer;

a semipermeable membrane surrounding the core and having at least one passageway there through; and

~~optionally,~~ a drug-containing water soluble and/or erodible external coat comprising a second amount of licofelone;

wherein 1) 20-30% of the licofelone is released within about 1 hour; 2) 25-65% of the licofelone is released within about 4 hours; 3) 47-83% of the licofelone is released within about 12 hours; and 4) at least 75% of the licofelone is released within 24 hours after exposure of the osmotic device to an aqueous environment; ~~,~~ and wherein the first and second amounts together comprise a therapeutically effective amount suitable for once daily administration to a subject.

2. Canceled

3. Canceled

4. (Currently amended) The osmotic device of claim 1 ~~any one of claims 1, 2 or 3, wherein the drug-containing coat is present,~~ further comprising an inert water soluble and/or erodible coating disposed between the semipermeable membrane and the drug-containing coating.

5. (Original) The osmotic device of claim 4, wherein the drug-containing coat is sprayed onto the inert coating.

6. (Currently amended) The osmotic device of claim~~s~~ 1 ~~or 2~~ wherein the licofelone is released from the core according to a first order or pseudo-first order rate for a period of at least 12 hours.

7. (Original) The osmotic device of claim 4 wherein the licofelone is released from the core according to a first order or pseudo-first order rate for a period of at least 12 hours.

8. (Currently amended) The osmotic device of claim~~s~~ 1 ~~or 2~~ wherein the licofelone is released from the core according to a zero order or pseudo-zero order rate for a period of at least 12 hours.

9. (Original) The osmotic device of claim 4 wherein the licofelone is released from the core according to a zero order or pseudo-zero order rate for a period of at least 12 hours.

10. (Currently amended) The osmotic device of claim~~s~~ 1 ~~or 2~~ wherein the licofelone is released from the core according to a sigmoidal release profile.

11. (Original) The osmotic device of claims 4 wherein the licofelone is released from the core according to a sigmoidal release profile.

12. (Currently amended) The osmotic device of claim 4, wherein the drug-containing water soluble and/or erodible external coat is present in an amount of at least about 25% wt. based upon the total weight of the osmotic device.

13. (Withdrawn) A method of treating a condition in a subject, the condition being responsive to treatment with licofelone, the method comprising the step of administering to the subject once per day an osmotic device

a core comprising a first amount licofelone and at least one osmotic agent or osmopolymer;

a semipermeable membrane surrounding the core and having at least one passageway there through; and

optionally, a drug-containing water soluble and/or erodible coat comprising a second amount of licofelone;

wherein at least 75% of the licofelone is released within 24 hours after exposure of the osmotic device to an aqueous environment, and wherein the first and second amounts together comprise a therapeutically effective amount suitable for once daily administration to a subject.

14. (Withdrawn) The method of claim 13, wherein the condition is selected from the group consisting of osteoarthritis, rheumatoid arthritis, an inflammation related disorder, spondyloarthopathies, gouty arthritis, osteoarthritis, systemic lupus erythematosus and juvenile arthritis, asthma, bronchitis, menstrual cramps, tendinitis, bursitis; skin related conditions such as psoriasis, eczema, burns and dermatitis; gastrointestinal conditions such as inflammatory bowel disease, Crohn's disease, gastritis, irritable bowel syndrome and ulcerative colitis; for the prevention or treatment of cancer, such as colorectal cancer; inflammation in vascular disease, migraine headache, periarteritis nodosa, thyroiditis, aplastic anemia, Hodgkin's disease, sclerodoma, rheumatic fever, type I diabetes, myasthenia gravis, multiple sclerosis, sarcoidosis, nephrotic syndrome, Behcet's syndrome, polymyositis, gingivitis, hypersensitivity, swelling

occurring after injury, myocardial ischemia, viral infections and cystic fibrosis; central nervous system disorders such as cortical dementias including Alzheimer's disease; allergic diseases; allergic rhinitis; respiratory distress syndrome; endotoxin shock syndrome; atherosclerosis; and central nervous system damage resulting from stroke, ischemia and trauma.

15. (Withdrawn) The method of claim 14, wherein: 1) at least 10% of the licofelone is released from the core within 4 hours; 2) at least 45% of the licofelone is released from the core within 12 hours; 3) at least 60% of the licofelone is released from the core within 16 hours; and 4) at least 75% of the licofelone is released from the core within 20 hours after exposure of the osmotic device to an aqueous environment.

16. (Withdrawn) The method of claim 14, wherein: 1) 20-30% of the licofelone is released within about 1 hours; 2) 25-65% of the licofelone is released within about 4 hours; 3) 47-83% of the licofelone is released within about 12 hours; and 4) at least 75% of the licofelone is released within about 24 hours after exposure of the osmotic device to an aqueous environment.

17. (Withdrawn) The method of claim 14, wherein the drug-containing coat is present, further comprising an inert water soluble and/or erodible coating disposed between the semipermeable membrane and the drug-containing coating.

18. (Withdrawn) The method of claim 14, wherein the licofelone is released from the core according to a first order or pseudo-first order rate for a period of at least 12 hours.

19. (Withdrawn) The method of claim 14, wherein the licofelone is released from the core according to a zero order or pseudo-zero order rate for a period of at least 12 hours.

20. (Withdrawn) The method of claim 14, wherein the licofelone is released from the core according to a sigmoidal release profile.

21. Canceled

22. Canceled

23. Canceled

24. Canceled

25. Canceled

26. Canceled

27. Canceled

28. Canceled

29. Canceled

30. Canceled

31. Canceled

32. (Currently amended) The osmotic device of claim ~~24~~ 1, wherein the drug-containing water soluble and/or erodible external coat is present in an amount of at least about 25% wt. based upon the total weight of the osmotic device.

33. (Withdrawn) A method of treating a condition in a subject, the condition being responsive to treatment with licofelone, the method comprising the step of administering to the subject once per day an osmotic device according to claim 21.

34. (Withdrawn) The method of claim 33, wherein the condition is selected from the group consisting of osteoarthritis, rheumatoid arthritis, an inflammation related disorder, spondyloarthopathies, gouty arthritis, osteoarthritis, systemic lupus erythematosus and juvenile arthritis, asthma, bronchitis, menstrual cramps, tendinitis, bursitis; skin related conditions such as psoriasis, eczema, burns and dermatitis; gastrointestinal conditions such as inflammatory bowel disease, Crohn's disease, gastritis, irritable bowel syndrome and ulcerative colitis; for the prevention or treatment of cancer, such as colorectal cancer; inflammation in vascular disease, migraine headache, periarteritis nodosa, thyroiditis, aplastic anemia, Hodgkin's disease, sclerodoma, rheumatic fever, type I diabetes, myasthenia gravis, multiple sclerosis, sarcoidosis, nephrotic syndrome, Behcet's syndrome, polymyositis, gingivitis, hypersensitivity, swelling occurring after injury, myocardial ischemia, viral infections and cystic fibrosis; central nervous system disorders such as cortical dementias including Alzheimer's disease; allergic diseases; allergic rhinitis; respiratory distress syndrome; endotoxin shock syndrome; atherosclerosis; and central nervous system damage resulting from stroke, ischemia and trauma.

35. (Withdrawn) The method of claim 34, wherein: 1) at least 10% of the licofelone is released from the core within 4 hours; 2) at least 45% of the licofelone is released from the core within 12 hours; 3) at least 60% of the licofelone is released from the core within 16 hours; and 4) at least 75% of the licofelone is released from the core within 20 hours after exposure of the osmotic device to an aqueous environment.

36. (Withdrawn) The method of claim 34, wherein: 1) 20-30% of the licofelone is released within about 1 hours; 2) 25-65% of the licofelone is released within about 4 hours; 3) 47-83% of the licofelone is released within about 12 hours; and 4) at least 75% of the licofelone is released within about 24 hours after exposure of the osmotic device to an aqueous environment.

37. (Withdrawn) The method of claim 34, wherein further comprising an inert water soluble and/or erodible coating disposed between the semipermeable membrane and the drug-containing coating.

38. (Withdrawn) The method of claim 34, wherein the licofelone is released from the core according to a first order or pseudo-first order rate for a period of at least 12 hours.

39. (Withdrawn) The method of claim 34, wherein the licofelone is released from the core according to a zero order or pseudo-zero order rate for a period of at least 12 hours.

40. (Withdrawn) The method of claim 34, wherein the licofelone is released from the core according to a sigmoidal release profile.

41. (Currently amended) The osmotic device of claim ~~21~~ 1, wherein all of the licofelone contained in the drug-containing water soluble and/or erodible external coat is released within 30 min after administration.

42. (Currently amended) The osmotic device of claim ~~21~~ 1, wherein all of the licofelone contained in the drug-containing water soluble and/or erodible external coat is released within 180 min after exposure to an aqueous environment.

43. (Currently amended) The osmotic device of claim 4 ~~or 24~~, wherein the inert water soluble and/or erodible coat is insoluble in the fluid of a first environment of use and soluble or erodible in the fluid of a second environment of use.

44. (Currently amended) The osmotic device of claim 1 ~~or 21~~, wherein the osmopolymer is selected from hydroxypropyl methylcellulose, polyethylene oxide and combinations thereof.

45. Canceled

46. Canceled

47. Canceled

48. (Currently amended) The osmotic device of claim 1 ~~or 21~~ comprising:

Ingredients	Amount (mg)
CORE	
Licofelone	150-600
Osmagent	35-150
Osmopolymer	20-90
Binder	1-6
Water soluble polymer	1-6
Plasticizer	1-5
Disintegrant	9-36
Glidant	0.5-3
Lubricant	1-5
COATING A (SEMIPERMEABLE COAT)	
Semipermeable film-forming polymer	15-30
Plasticizer	0.5-2.0
COATING B (INERT COAT)	
Opaquant	1-5
Water erodible material	3-10
Water soluble polymer	2-6
COATING C (~~OPTIONAL,~~ DRUG-CONTAINING COAT)	
Licofelone	50-200
Water soluble polymer	10-50
Water erodible polymer	10-45
Plasticizer	3-15
Glidant	1-5
COATING D (OPTIONAL, FINISH COAT)	
Water soluble polymer	7-20

49. (Previously added) The osmotic device of claim 48 wherein the osmagent is sodium chloride.

50. (Previously added) The osmotic device of claim 48 wherein the osmopolymer is polyethylene oxide.

51. (Previously added) The osmotic device of claim 48 wherein the water soluble polymer in the core is hydroxypropyl methylcellulose.

52. (Previously added) The osmotic device of claim 48 wherein the water erodible material in the inert coat is selected from poly(vinylpyrrolidone)-(vinyl acetate) copolymer and povidone.